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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,941	04/30/2001	James F. Hemerick	6530.0278	8636

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EXAMINER	
THALER, MICHAEL H	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,941	HEMERICK ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,45,47-57,59-65,67 and 68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,45,47-57,59-65,67 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 22, 2004 has been entered.

Claims 11, 45, 48, 50-55 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of either Sullivan et al. (5,968,052) or Torossian (5,851,210). Winston et al. show outer tubular structure 20, inner elongated structure 12, stent accommodating area (just distal to flange 14) and a plurality of external tubular structure contact areas (flanges 14) which slide against the interior surface of the outer tubular structure 20 since they are shown contacting one another in figures 1, 2 and 4. Winston et al. fail to disclose a translucent region at the distal end of the outer tubular structure 20. However, Sullivan et al. teach that the distal end region of the outer tubular structure 14 of a stent delivery system should transmit light therethrough so that the stent therein may be visually inspected (col. 3, lines 24-33). It would have been obvious to enable the

distal end region of the outer tubular structure 20 of Winston et al. to transmit light therethrough so that it too would have this advantage. The transparent material is inherently translucent to some extent since no material is perfectly transparent. Further, the length of this translucent region substantially coincides with a constrained length of the stent. Alternatively, Torossian teaches that the distal end region of the outer tubular structure 40 (as well as the remainder of the outer tubular structure) of a stent delivery system should be translucent apparently in order transmit light therethrough so that the stent therein may be visually inspected (col. 5, lines 43-49). It would have been obvious to enable the distal end region of the outer tubular structure 20 of Winston et al. to transmit light therethrough so that it too would have this advantage. Further, the length of this translucent distal end region substantially coincides with a constrained length of the stent. As to claims 48 and 50, Winston et al. fail to disclose at least one marker band on the inner elongated structure. However, Sullivan et al. teach that the inner elongated structure of a stent delivery system should include a marker band (e.g. 36) in order to provide an indication of the position of the stent (col. 3, lines 1-13). It would have been obvious to include a marker band on the inner elongated structure 12 of

Winston et al. so that it too would have this advantage. Alternatively, Torossian teaches that the inner elongated structure of a stent delivery system should include a marker band (e.g. 35) in order to provide an indication of the position of the stent (col. 5, lines 32-38). It would have been obvious to include a marker band on the inner elongated structure 12 of Winston et al. so that it too would have this advantage. As to claim 51, Winston et al. fail to disclose the steps of retracting the stent back into the outer tubular structure and then repositioning the stent delivery system. However, retracting the Winston et al. stent back into the outer tubular structure and then repositioning the stent delivery system when it is determined that the stent is not initially properly positioned would have been obvious since it was well known in this art to so retract and reposition stents for this reason. As to claim 53, Winston et al. fail to show Pellethane as the material for the inner tubular structure. However, using Pellethane as the material for the inner tubular structure would have been obvious since it is well known as a desirable material for this use as indicated on page 2, lines 8-10 of applicant's specification. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of either Sullivan et al. (5,968,052) or Torossian (5,851,210) as applied to claims 11, 45, 48, 50-55 and 61-63 above, and further in view of Hofmann et al. (5,810,837). Winston et al. fail to disclose a gap between an external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20. However, Hofmann et al. teach that there should be a gap between the external surface of the external tubular structure 10 and the inner surface of the outer tubular structure 3 (the outer diameter C of member 10 is 4.5 mm while the inner diameter B of outer tubular structure 3 is 4.6 mm as indicated in col. 4, line 38) apparently in order to insure that the inner elongated structure 10, 9, 7 is able to slide relative to outer tubular structure 3 with minimal friction. It would have been obvious to provide such a gap between the Winston et al. external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20 so that it too would have this advantage.

Claims 56, 57, 59, 60, 64, 65, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of either Sullivan et al. (5,968,052) or Torossian (5,851,210) as applied to claims 11, 45, 48, 50-55 and

61-63 above, and further in view of Burns (5,100,381). Winston et al. fail to disclose each subsequently proximal external structure 14 increasing in durometer. However, Burns teaches that the distal portion of a catheter should be more flexible than the proximal portion in order to allow the catheter to be advanced through the rather tortuous paths of the arteries while maintaining pushability (col. 2, lines 30-34 and col. 3, line 65 to col. 4, line 6). It would have been obvious to make the distal portion of the Winston et al. catheter 12 more flexible than the proximal portion so that it too would have this advantage. With this modification, the distal portion of the Winston et al. catheter 12 (which includes a distal flange 14) would be made of a material which is more flexible (with a low durometer) than a proximal portion of the catheter 12 (which includes a proximal flange 14) made of a high durometer, stiffer material.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note col. 4, lines 16-19 of Bui et al. (6,413,269), col. 2, lines 50-57 of Bachmann et al. (5,954,729), col. 8, lines 13-14 of Poncet (5,833,694), col. 8, lines 1-2 of Mikus et al. (5,830,179), col. 3, lines 64-66 of Mikus et al. (6,517,569) and col. 6, lines 63-65 of Igaki (5,817,100).

Applicant's arguments with respect to claims 11, 45, 47-57, 59-65, 67 and 68 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
6/28/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731